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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,949	01/04/2001	Justin McCarthy	SCIOS.012A	4532

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KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH, CA 92660

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 12/06/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,949

Applicant(s)

MCCARTHY ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to a method for identifying inhibitors of neuronal degeneration transfecting eukaryotic cells with a polynucleotide encoding a Par-4-polypeptide, classified in class 435, subclass 455, for example.
 - II. Claims 1, 18-19, drawn to a method for identifying inhibitors of neuronal degeneration transfecting eukaryotic cells with a polynucleotide encoding a Par-4-polypeptide and administering the inhibitor to a patient, classified in class undetermined, subclass undetermined.
 - III. Claims 20-22, drawn to a method for identifying inhibitors of neuronal degeneration transfecting eukaryotic cells with a polynucleotide encoding an NF- κ B dependent reporter construct, classified in class 435, subclass 455, for example.
 - IV. Claim 23, drawn to a method for identifying inhibitors of Par-4-polypeptide expression, classified in class 435, subclass 455, for example.
 - V. Claims 24-29, drawn to a method for identifying inhibitors of Par-4-polypeptide expression comprising exposing the transfected cells to a pre-apoptotic agent, classified in class 435, subclass 455, for example.

- VI. Claims 30-31, drawn to a method for identifying inhibitors of neuronal degeneration using cells expressing PS and Par-4-polypeptide, classified in class undetermined, subclass undetermined, for example.
- VII. Claims 32-33, drawn to a method for identifying inhibitors of neuronal degeneration using cells expressing PS and Par-4-polypeptide and monitoring the level of ξ PKC phosphorylation, classified in class undetermined, subclass undetermined, for example.
- IIIX. Claims 34-36, drawn to a method for identifying inhibitors of neuronal degeneration using cells expressing PS and Par-4-polypeptide and monitoring the levels of IKK phosphorylation, classified in class undetermined, subclass undetermined, for example.
- IX. Claim 37, drawn to a method for identifying inhibitors of neuronal degeneration transfecting eukaryotic cells with a polynucleotide comprising Par-4-polypeptide promoter region fused to a reporter gene, classified in class 435, subclass 355, for example.
- X. Claims 38-45, drawn to nucleic acids, vectors, host cells and methods of recombinant protein production, classified in class 435, subclass 69.1, for example.
- XI. Claims 46-47, drawn to a method for identifying inhibitors of neuronal degeneration using cells expressing PS and Par-4 and monitoring ξ PKC level, classified in class undetermined, subclass undetermined, for example.

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- XII. Claim 48, drawn to a method of inhibiting PAR-4 activity, classified in class 435, subclass 355, for example.
- XIII. Claims 49-50, drawn to a method for identifying inhibitors of neuronal degeneration in a mammal, classified in class 514, subclass 44, for example.
- XIV. Claim 51, drawn to inhibitors of neuronal degeneration, classified in class undetermined, subclass undetermined.
- XV. Claim 52, drawn to a process of obtaining a compound for the treatment, classified in class undetermined, subclass undetermined, for example.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I, II, III, IV, V, VI, VII, IIX, IX, XI, XII, XIII and XV are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

- 3. Inventions (I, V, IX, XII, XIII) and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group IX could be used in an entirely different manner such as for the production of proteins rather than in the methods of Groups (I, V, IX, XII, XIII).

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4. Inventions (II, II, IV, VI, VII, IIX, XI, XIV, XV) and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the nucleic acids of Group X are not required for the inventions of Groups (II, II, IV, VI, VII, IIX, XI, XIV, XV).
5. Inventions (I, III-XIII and XV) and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the compounds of Group XIV are not required for the inventions of Groups (I, III-XIII and XV).
6. Inventions II and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of Group XIV could be used in an entirely different manner such as for the screening the said compounds on different cell lines or primary cultures rather than in the method of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject

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matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

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published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
December 3, 2001

OC

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud